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Mail Stop Amendment  
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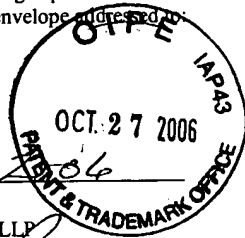
On

OCTOBER 23, 2006

TOWNSEND and TOWNSEND and CREW LLP

By:

*Kimberly Rose*



PATENT  
Attorney Docket No.: 016930-000816US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

Heidrun Engler et al.

Application No.: 10/055,863

Filed: January 22, 2002

For: COMPOSITIONS AND METHODS  
FOR ENHANCING DELIVERY OF  
THERAPEUTIC AGENTS TO CELLS

Confirmation No.: 4929

Examiner: Elli Peslev

Art Unit: 1623

SUPPLEMENTAL INFORMATION  
DISCLOSURE STATEMENT UNDER  
37 CFR §1.97 and §1.98

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

The references cited on attached form PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. The following copies of the references [in compliance with the requirements of 37 CFR §1.98(a)(2)] are enclosed:

A13. BLAESE et al., "Vectors in Cancer Therapy: How Will They Deliver?" Cancer Gene Therapy, 1995, Vol. 2, No. 4, pp. 291-297;

A14. BRAMSON et al., "The USE of Adenoviral Vectors for Gene Therapy and Gene Transfer *in Vivo*," Current Opinion in Biotechnology, 1995, Vol. 6, pp. 590-595;

10/30/2006 SDENBOB1 00000002 201430 10055863

02 FC:1806 180.00 DA

- A15. van BUREN et al., "Inactivation of Human Immunodeficiency Virus Type 1 by Alcohols," October 1994, Vol. 28, No. 2, pp. 137-148;
- A16. CALBIOCHEM, "Biochemical/Immunochemical 1992 Catalog," Calbiochem Biochemicals, 1992, pp. 322, 05, 65, 259;
- A18. CORDIER et al., "Complete Recovery of Mice from a Pre-established Tumor by Direct Intratumoral Delivery of an Adenovirus Vector Harboring the Murine IL-2 Gene," Gene Therapy, 1995, Vol. 2, pp. 16-21.
- A19. CROYLE et al., "Development of Formulations that Enhance Physical Stability of Viral Vectors for Gene Therapy," Gene Therapy, 2001, Vol. 8, pp. 1281-1290;
- A21. CULVER et al., "Gene Therapy for Cancer," Treatment Information Group (TIG), May 1994, Vol. 10, No. 5, pp. 174-178;
- A22. DESCAMPS et al., "Strategies for Cancer Gene Therapy Using Adenoviral Vectors," Journal of Molecular Medicine, 1996, Vol. 74, pp. 183-189.
- A25. GARDLIK et al. "Vectors and Delivery Systems in Gene Therapy," Medical Science Monitor, 2005, Vol. 11, No. 4, pp. RA110-121;
- A26. GOEDDEL, et al., "The Structure of Eight Distinct Cloned Human Leukocyte Interferon cDNAs," Nature, 1981, Vol 290, pp. 20-26;
- A27. GONCALVES, Manuel A.F.V., "A Concise Peer Into the Background, Initial Thoughts and Practices of Human Gene Therapy," BioEssays, 2005, Vol. 27, pp. 506-517;
- A29. HADDADA et al., "Gene Therapy Using Adenovirus Vectors," Current Topics in Microbiology and Immunology, 1995, Vol. 199, No. 3, pp. 297-306;
- A30. HADDADA et al., "Adenoviral Interleukin-2 Gene Transfer into P815 Tumor Cells Abrogates Tumorigenicity and Induces Antitumoral Immunity in Mice," Human Gene Therapy, 1993, Vol 4, pp. 703-711;
- A31. HARRIS et al., "Adenovirus-mediated p53 Gene Transfer Inhibist Growth of Human Tumor Cells Expressing Mutant p53 Protein," Cancer Gene Therapy, 1996, Vol. 3, No. 2, pp. 121-130;
- A34. O'DONNELL et al., "Salvage Intravesical Therapy with Interferon-  $\alpha$ 2B Plus Low Dose Bacillus Calmette-Guerin is Effective in Patients with Superficial Bladder Cancer in Whol Bacillus Calmette-Guerin Alone Previously Failed," The Journal of Urology, October 2001, Vol 166, pp. 1300-1305.

In accordance with 37 CFR §1.98(d), copy of the references can be found in  
Application No. 08/889,355, filed July 8, 1997 (Attorney Docket No. 016930-000811US):

A23. ECK et al., "Gene Based Therapy," The Pharmacological Basis of Therapeutics,  
1995, 9th edition, Goodman & Gilman, pp. 77-101.

In accordance with 37 CFR §1.98(d), copies of the references can be found in  
Application No. 10/454,662, filed June 3, 2003 (Attorney Docket No. 016930-000815US).

A10. WO 1995/10265 published on April 20, 1995;

A11. WO 1997/11682 published on April 3, 1997;

A12. ASSOCIATED PRESS, "One Way to Kill Cancer: Give a Cold," The Augusta Chronicle, May 20, 1997, (accessed by PTO on World Wide Web at CNN.com on May 22, 1997);

A17. CONNOR et al., "Identification of Polyamides that Enhance Adenovirus-Mediated Gene Expression in the Urothelium," Gene Therapy, 2001, Vol. 8, pp. 41-48;

A20. CRYSTAL et al., "Transfer of Genes to Humans: Early Lessons and Obstacles to Success," Science, 1995, Vol. 270, pp.404-410;

A24. FRIEDMAN, Theodore, "Gene Therapy of Cancer Through Restoration of Tumor-Suppressor Functions?" Cancer, 1992, Vol. 74, pp. 183-189;

A28. GUZMAN et al., "Efficient and Selective Adenovirus-Mediated Gene Transfer into Vascular Neointima" Circulation, 1993, Vol. 88, Issue 4, No. 11, pp. 1-80;

A32. HJEMELAND et al., "A New Class of Nonionic Detergents with a Gluconamide Polar Group," Analytical Biochemistry Vol. 130, pp. 485-490;

A33. LEDLEY, Fred D. "Nonviral Gene Therapy: The PRomise of Genes as Pharmaceutical Products" Human Gene Therapy, September 1995, Vol. 6, pp. 1129-1144;

A35. ORKIN et al., "Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy," Issued by the U.S. National Institutes of Health, Dec. 1995;

A36. PAGLIARO et al., "Repeated Intravesical Instillations of an Adnoviral Vector in Patients with Locally Advanced Bladder Cancer: A Phase I Study of p53 Gene Therapy," Journal of Clinical Oncology, June 15, 2003, Vol. 21, No. 12, pp. 2247-2253;

A37. SCHMOLKA, Irving R., "A Comparison of Block Copolymer Sufactant Gels<sup>1</sup>,"  
JAOCS, March 1991, Vol. 68, no. 3, pp. 206-209;

A38. YAMASHITA et al., "Syn3 Provides High Levels of Intrvescal Adnoviral-Mediated  
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Baldder Cancer," Cancer Gene Therapy, 2002, Vol. 9, pp. 681-686.

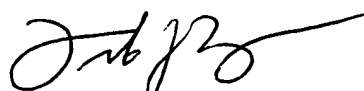
It is respectfully requested that the cited references be expressly considered  
during the prosecution of this application, and the references be made of record therein and  
appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the  
information and references cited are prior art merely because they are in this statement and no  
representation is being made that a search has been conducted or that this statement encompasses  
all the possible relevant information.

This IDS is being filed before the mailing date of the final Office Action or  
Notice of Allowance.

Please charge the IDS fee of \$180 to Deposit Account No. 20-1430. Please  
deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,



Frank J. Mycroft  
Reg. No. 46,946

TOWNSEND and TOWNSEND and CREW LLP  
Two Embarcadero Center, Eighth Floor  
San Francisco, California 94111-3834  
Tel: 925-472-5000  
Fax: 925-472-8895  
FJM:aei



Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).

**FREE TRANSMITTAL**  
**For FY 2006**☐ Applicant claims small entity status. See 37 CFR 1.27**TOTAL AMOUNT OF PAYMENT** (\$) 180**Complete if Known**

Application Number	10/055,863
Filing Date	January 22, 2002
First Named Inventor	Engler, Heidrun
Examiner Name	Elli Peselev
Art Unit	1623
Attorney Docket No.	016930-000816US

**METHOD OF PAYMENT** (check all that apply)☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_☒ Deposit Account Deposit Account Number: 20-1430 Deposit Account Name: Townsend and Townsend and Crew LLP

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Small Entity	Fee (\$)	Small Entity	Fee (\$)	Small Entity	Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES****Fee Description**

Each claim over 20 (including Reissues)

Each independent claim over 3 (including Reissues)

Multiple dependent claims

Small Entity	
Fee (\$)	Fee (\$)
50	25
200	100
360	180
Multiple Dependent Claims	
Fee (\$)	Fee Paid (\$)

Total Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
_____	_____	_____	_____

-20 or HP = \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

HP = highest number of total claims paid for, if greater than 20

Indep. Claims	Extra Claims	Fee (\$)	Fee Paid (\$)
_____	_____	_____	_____

-3 or HP = \_\_\_\_\_ x \_\_\_\_\_ = \_\_\_\_\_

HP = highest number of independent claims paid for, if greater than 3

**3. APPLICATION SIZE FEE**

If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fee Paid (\$)
_____	_____	_____	_____	_____

- 100 = \_\_\_\_\_ / 50 = \_\_\_\_\_ (round up to a whole number) x \_\_\_\_\_ = \_\_\_\_\_

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)

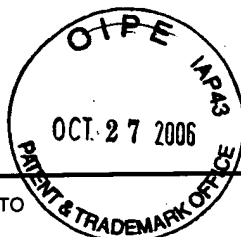
Other (e.g., late filing surcharge): Submission of Information Disclosure Stmt

**Fees Paid (\$)**

180

**SUBMITTED BY**

Signature		Registration No. (Attorney/Agent)	46,946	Telephone	925-472-5000
Name (Print/Type)	Frank J. Mycroft			Date	October 23, 2006



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

1

of

6

**Complete if Known**

Application Number	10/055,863
Filing Date	January 22, 2002
First Named Inventor	Engler, Heidrun
Art Unit	1623
Examiner Name	Elli Peseev
Attorney Docket Number	016930-000816US

**U.S. PATENT DOCUMENTS**

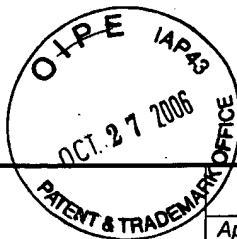
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code <sup>2</sup> (if known)			
	A1	US-2003-0170216	09/11/2003	Ihnat et al.	
	A2	US-2003-0211598	11/13/2003	Engler et al.	
	A3	US-2004-0014709	01/22/2004	Engler et al.	
	A4	US-2005-0025742	02/03/2005	Engler et al.	
	A5	US-2006-0199782	09/07/2006	Engler et al.	
	A6	US-6,165,779	12/26/2000	Engler et al.	
	A7	US-6,312,681	11/6/2001	Engler et al.	
	A8	US-6,392069	05/21/2002	Engler et al.	
	A9	US-7,002,027	02/21/2006	Engler et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	A10	WO	95/10265	A1	04/20/1998	Cytrx Corporation		
	A11	WO	97/11682	A2	04/03/1997	University of Pittsburgh		

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Kind Codes of U.S. Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.



<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/055,863
				Filing Date	January 22, 2002
				First Named Inventor	Engler, Heidrun
				Art Unit	1623
				Examiner Name	Elli Peselev
Sheet	2	of	6	Attorney Docket Number	016930-000816US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	A12	ASSOCIATED PRESS, "One Way to Kill Cancer: Give a Cold," <u>The Augusta Chronicle</u> , May 20, 1997, (accessed by PTO on World Wide Web at CNN.com on May 22, 1997).	<input type="checkbox"/>
	A13	BLAESE et al., "Vectors in Cancer Therapy: How Will They Deliver?" <u>Cancer Gene Therapy</u> , 1995, Vol. 2, No. 4, pp. 291-297.	<input type="checkbox"/>
	A14	BRAMSON et al., "The Use of Adenoviral Vectors for Gene Therapy and Gene Transfer <i>in Vivo</i> ," <u>Current Opinion in Biotechnology</u> , 1995, Vol. 6, pp. 590-595.	<input type="checkbox"/>
	A15	van BUREN et al., "Inactivation of Human Immunodeficiency Virus Type 1 by Alcohols," October 1994, Vol. 28, No. 2, pp. 137-148.	<input type="checkbox"/>
	A16	CALBIOCHEM, "Biochemical/Immunochemical 1992 Catalog," <u>Calbiochem Biochemicals</u> , 1992, pp. 322, 05, 65, 259.	<input type="checkbox"/>
	A17	CONNOR et al., "Identification of Polyamides that Enhance Adenovirus-Mediated Gene Expression in the Urothelium," <u>Gene Therapy</u> , 2001, Vol. 8, pp. 41-48.	<input type="checkbox"/>
	A18	CORDIER et al., "Complete Recovery of Mice from a Pre-established Tumor by Direct Intratumoral Delivery of an Adenovirus Vector Harboring the Murine IL-2 Gene," <u>Gene Therapy</u> , 1995, Vol. 2, pp. 16-21.	<input type="checkbox"/>
	A19	CROYLE et al., "Development of Formulations that Enhance Physical Stability of Viral Vectors for Gene Therapy," <u>Gene Therapy</u> , 2001, Vol. 8, pp. 1281-1290.	<input type="checkbox"/>
	A20	CRYSTAL et al., "Transfer of Genes to Humans: Early Lessons and Obstacles to Success," <u>Science</u> , 1995, Vol. 270, pp.404-410.	<input type="checkbox"/>
	A21	CULVER et al., "Gene Therapy for Cancer," <u>Treatment Information Group (TIG)</u> , May 1994, Vol. 10, No. 5, pp. 174-178.	<input type="checkbox"/>
	A22	DESCAMPS et al., "Strategies for Cancer Gene Therapy Using Adenoviral Vectors," <u>Journal of Molecular Medicine</u> , 1996, Vol. 74, pp. 183-189.	<input type="checkbox"/>
	A23	ECK et al., "Gene Based Therapy," <u>The Pharmacological Basis of Therapeutics</u> , 1995, 9th edition, Goodman & Gilman, pp. 77-101.	<input type="checkbox"/>
Examiner Signature			Date Considered

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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.



<b>Substitute for form 1449B/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (Use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/055,863
				Filing Date	January 22, 2002
				First Named Inventor	Engler, Heidrun
				Art Unit	1623
				Examiner Name	Elli Peselev
Sheet	3	of	6	Attorney Docket Number	016930-000816US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>	
	A24	FRIEDMAN, Theodore, "Gene Therapy of Cancer Through Restoration of Tumor-Suppressor Functions?" <u>Cancer</u> , 1992, Vol. 74, pp. 183-189.	<input type="checkbox"/>	
	A25	GARDLIK et al. "Vectors and Delivery Systems in Gene Therapy," <u>Medical Science Monitor</u> , 2005, Vol. 11, No. 4, pp. RA110-121.	<input type="checkbox"/>	
	A26	GOEDEL, et al., "The Structure of Eight Distinct Cloned Human Leukocyte Interferon cDNAs," <u>Nature</u> , 1981, Vol 290, pp. 20-26.	<input type="checkbox"/>	
	A27	GONCALVES, Manuel A.F.V., "A Concise Peer Into the Background, Initial Thoughts and Practices of Human Gene Therapy," <u>BioEssays</u> , 2005, Vol. 27, pp. 506-517.	<input type="checkbox"/>	
	A28	GUZMAN et al., "Efficient and Selective Adenovirus-Mediated Gene Transfer into Vascular Neointima" <u>Circulation</u> , 1993, Vol. 88, Issue 4, No. 11, pp. 1-80.	<input type="checkbox"/>	
	A29	HADDADA et al., "Gene Therapy Using Adenovirus Vectors," <u>Current Topics in Microbiology and Immunology</u> , 1995, Vol. 199, No. 3, pp. 297-306.	<input type="checkbox"/>	
	A30	HADDADA et al., "Adenoviral Interleukin-2 Gene Transfer into P815 Tumor Cells Abrogates Tumorigenicity and Induces Antitumoral Immunity in Mice," <u>Human Gene Therapy</u> , 1993, Vol 4, pp. 703-711.	<input type="checkbox"/>	
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	A33	LEDLEY, Fred D., "Nonviral Gene Therapy: The Promise of Genes as Pharmaceutical Products" <u>Human Gene Therapy</u> , September 1995, Vol. 6, pp. 1129-1144.	<input type="checkbox"/>	
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Examiner Signature		Date Considered	
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/055,863
Filing Date	January 22, 2002
First Named Inventor	Engler, Heidrun
Art Unit	1623
Examiner Name	Elli Peselev
Attorney Docket Number	016930-000816US

Sheet 4

of

6

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	A35	ORKIN et al., "Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy," Issued by the U.S. National Institutes of Health, Dec. 1995.	<input type="checkbox"/>
	A36	PAGLIARO et al., "Repeated Intravesical Instillations of an Adenoviral Vector in Patients with Locally Advanced Bladder Cancer: A Phase I Study of p53 Gene Therapy," <u>Journal of Clinical Oncology</u> , June 15, 2003, Vol. 21, No. 12, pp. 2247-2253.	<input type="checkbox"/>
	A37	SCHMOLKA, Irving R., "A Comparison of Block Copolymer Sufactant Gels <sup>1</sup> ," <u>JAOCS</u> , March 1991, Vol. 68, no. 3, pp. 206-209.	<input type="checkbox"/>
	A38	YAMASHITA et al., "Syn3 Provides High Levels of Intravesical Adenoviral-Mediated Gene Transfer for Gene Therapy of Genetically Altered Urothelium and Superficial Bladder Cancer," <u>Cancer Gene Therapy</u> , 2002, Vol. 9, pp. 681-686.	<input type="checkbox"/>

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